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Minnesota Board of Pharmacy

University Park Plaza
2829 University Ave SE, Suite 530
Minneapolis, MN 55414-3251
www.phcybrd.state.mn.us

Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Actions

During the months of December 2001, and January and February 2002, the Minnesota Board of Pharmacy finalized the following disciplinary actions on its licensees.

Stock, Jeannette A., License #111503-3. License was revoked as a result of a notice from the Department of Revenue that she was delinquent in payment of taxes. Revocation remains in effect until a clearance certificate is issued by the Minnesota Department of Revenue.

DEA Policy Regarding Information that can be Changed on a Schedule II Prescription

The Board continues to periodically get questions from pharmacists regarding Schedule II prescriptions and what, if any, pieces of information can be changed on a Schedule II prescription without requiring a new prescription from the practitioner. The following information is taken from a Drug Enforcement Administration (DEA) Web site and nicely addresses the issue.

The majority of changes can be made only after the pharmacist contacts the prescribing practitioner. After consultation with the prescribing practitioner, the pharmacist is permitted to change the patient's address, drug strength, drug quantity, and directions for use. The pharmacist is permitted to make information additions that may be provided by the patient or bearer such as the patient's address, and such additions should be verified. The pharmacist may also add the dosage form to the prescription order after verification with the prescribing practitioner.

The pharmacist is never permitted to make changes to the patient's name, controlled substances prescribed (except for generic substitution permitted by State Law), or the prescriber's signature. These types of changes challenge the necessity of the original prescription and would require a new prescription from the prescribing practitioner.

In those cases where a prescriber either omits the strength, quantity, or directions, or where the pharmacist doing prospective drug utilization review discovers an error in any of these required elements, this policy allows the problem to be dealt with by a telephone call rather than a trip back to the prescriber's office. The pharmacist should always document the time and date that the prescriber was contacted about the correction, and should always ask the prescriber to document the change in the patient's chart so that both the prescriber and the pharmacist have a record of the conversation. Please contact the local DEA office or the State Board of Pharmacy if you have any questions about this policy.

Board Receives Comments on Proposed Rules

Readers of this *Newsletter* perhaps will recall that in the last issue a notice of proposed rule making was included. The period for receiving public comment on the proposed rules is now over. The Board will soon be reviewing the comments it received and developing the final language of the rule package. One item of the proposed rule package received more than 25 requests for a public hearing. As a result, it will be withdrawn from the final rule package when the Board develops the final language. The proposed rule that received more than 25 requests for a public hearing was the proposed language relating to lunch breaks for pharmacists, which would have allowed pharmacists to have lunch breaks and, if the pharmacists were comfortable in doing so, would allow the pharmacy to remain open and allow technicians to continue to perform their part of the dispensing operation. The proposal required the pharmacist to check all work done by the technician in the absence of the pharmacist and prohibited the technician from providing prescriptions to patients when patient counseling was called for.

Because the Board received more than 25 requests for a public hearing on that specific rule section, the Board cannot adopt that section as a part of the overall package.

The Board determined the final language on the remaining sections of the rule package at its March meeting. A description of the final language on the remaining sections will be published in the July *Newsletter*.

Governor Appoints New Board Member

Members of the Minnesota Board of Pharmacy serve four-year terms and are appointed by the governor. Each year in January, one-fourth of the current Board members have terms that expire. In January of this year, the terms of Carl Benson, a community pharmacist from Morris, Minn, and Jean Lemberg, a public member from Arden Hills, Minnesota, expired.

Governor Jesse Ventura reappointed Ms Jean Lemberg to an additional four-year term and appointed Mr Gary Schneider, a pharmacist from Plymouth, Minn, to replace Mr Benson.

Mr Schneider is a former community pharmacy owner who is currently working for Gallipot Laboratories, a wholesaler of prescription compounding supplies and chemicals.

Please join the Board in congratulating Mr Schneider and in offering our sincere appreciation to Carl Benson for his eight years of dedicated service to the Board.

DEA Issues Guidance on Dispensing Controlled Substances to Assist Suicide

The US Drug Enforcement Administration (DEA) issued a guidance notice in the November 9, 2001 *Federal Register* stating that the Attorney General determined that assisting suicide is not a legitimate medical purpose within the meaning of 21 CFR 1306.04 (2001) and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the Controlled Substances Act. According to the notice, such conduct by a physician registered to dispense controlled substances may render his registration inconsistent with the public interest and subject to possible suspension or revocation. The Attorney General's conclusion applies regardless of whether state law authorizes or permits such conduct by practitioners or others and regardless of the condition of the person whose suicide is assisted. This notice may be found at the DEA's Web site at www.deadiversion.usdoj.gov/fed_regs/notices/2001/fr1109.htm.

For further information contact Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone 202/307-7297.

FDA Issues Guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

The US Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) issued a guidance to other federal agencies in November 2001 that recognizes potassium iodide (KI) as a thyroid blocking agent in radiation emergencies.

Based upon thorough research, FDA has proposed lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than it recommended in 1982. FDA continues to recommend that radiation emergency response plans include, in the event of a radiation emergency, provisions for informing the public about the magnitude of the radiation hazard, about the manner of use of KI and its potential benefits and risks, and for medical contact, reporting, and assistance systems. FDA also emphasizes that emergency response plans and any systems for ensuring availability of KI to the public should recognize the critical importance of KI administration in advance of exposure to radioiodine.

As in the past, FDA continues to work in an ongoing fashion with manufacturers of KI to ensure that high-quality, safe, and effective KI products are available for purchase by consumers as well as by state and local governments wishing to establish stores for emergency distribution. FDA emphasizes that the use of KI should be an adjunct to evacuation (itself not always feasible), sheltering, and control of foodstuffs. The guidance may be viewed in its entirety on the FDA's Web site at www.fda.gov/cder/guidance/4825fnl.htm.

USP Launches Dietary Supplement Verification Program

The US Pharmacopeia (USP) recently announced the availability of its Dietary Supplement Verification Program (DSVP). Developed in response to the USP Convention membership's resolutions in 1995 and 2000, urging the USP to develop standards and analytical methods for dietary supplements, and, in particular, botanicals, the USP will work directly with dietary supplement companies to verify the integrity of those they submit to USP.

Each product will be evaluated on the following criteria:

- Quality control and manufacturing data review;
- Laboratory evaluation of product samples and regular monitoring; and
- Evaluation of manufacturers' quality systems by means of an audit.

Based on USP's assessment of the manufacturer's capability to produce a dietary supplement and testing to USP standards, USP will issue a certification mark that the manufacturer can use on the dietary supplement container label. According to USP, the presence of this mark indicates that the product contains the dietary supplement ingredient in the designated amount, meets acceptable limits of undesirable elements, and is manufactured appropriately.

While the DSVP complements the US Food and Drug Administration's regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994 (DSHEA), USP notes that it does not address health or other claims provided under the DSHEA. The USP Council of Experts' Dietary Supplement Information Expert Committee will initially review all products sub-

ompliance News to a particular state or jurisdiction should not be
ining the law of such state or jurisdiction.)

mitted for verification in instances where safety concerns have been raised.

USP anticipates that the DSVP mark will offer patients a basis for confidence in the dietary supplement they use and that health care professionals will have the assurance that products bearing the distinctive mark and the words "USP Verified" have satisfied rigorous scientific criteria and assessments.

For more information about the DSVP, visit the USP's Web site at www.usp.org.

Inappropriate Designation of Dosage Form is a Common Source of Error

This is the first of a new feature about medication errors written by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with US Pharmacopeia (USP) and Food and Drug Administration (FDA) in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Road, Huntingdon Valley, PA 19006. Phone 215/947-7797. E-mail: ismpinfo@ismp.org.

Confusion seems to reign whenever a medication is available in oral dosage forms with different release rates. The situation is worse when there are two or more "delayed" release formulations for the same product. We recently heard about four cases where community pharmacists dispensed **METADATE ER** instead of **METADATE CD**. Both are methylphenidate hydrochloride extended-release, but they are not substitutable. The CD product is a once-a-day capsule with biphasic release. There is an initial rapid release of methylphenidate, then a continuous release phase, resulting in school-day-long control of attention deficit hyperactivity disorder (ADHD) symptoms. The ER product is a tablet given two to three times a day. It may be titrated to remove the need for midday dosing. Each of the pharmacists involved in the error were not aware that the Metadate CD product existed.

Recently, Novartis received FDA approval for another once-a-day methylphenidate, **RITALIN LA**. This will be available on the market along with **RITALIN SR**, another sustained release dosage form. Thus, confusion can be expected between these two formulations. Last year we also learned about similar confusion between Abbott's **DEPAKOTE ER** (divalproex sodium extended release) and **DEPAKOTE** (divalproex sodium delayed release).

To make matters worse, it is common for physicians to prescribe an extended release product without the appropriate name or suffix. Also, some products have numerous suffixes to differentiate formulations of the same drug. For example, suffixes for various diltiazem products include SR, CD, XR, and XT. As one colleague recently stated, "Between all the generics and brands trying to differentiate themselves, it is all but impossible to keep from making mistakes."

Nomenclature standards need to be established to allay confusion between various formulations of the same drug. Perhaps a unique brand name might be needed to designate a different formulation property, as was done with **NEORAL** (cyclosporine modified) and **SANDIMMUNE** (cyclosporine).

Meanwhile, carefully select new medications with the knowledge that confusion between different formulations and suffixes is likely. Build alerts into computer systems and mark drug containers to warn pharmacists and technicians about the differences. Some pharmacists design computer mnemonics to separate the different formulations on their computer screens.

Keep in mind that prescriber confusion between the various drug name suffixes has also been reported. New prescriptions for any of these medications may need to be verified. When prescribing one of these medications, physicians should alert patients to possible confusion between the various formulations and suffixes so they can help identify an error before taking the medication when they take the opportunity to speak with the pharmacist during counseling. Pharmacists should encourage patients to request such interaction with their physicians.

FDA is aware of these problems and will be examining ways to improve trademark nomenclature. An industry guidance has been promised for later this year.

Complaints Continue to Increase

During 2001, the Board of Pharmacy received 93 written complaints relating to professional services rendered by pharmacists. In the month of January 2002, the Board received 17 complaints. If this rate continues for the rest of the year, the Board will not only break the 100-complaint level for the first time, but will also break the 200-complaint level.

While not all complaints received by the Board relate to dispensing errors, medication-dispensing errors are by far the largest single category.

While it seems as if articles are written for every *Newsletter* relating to medication dispensing errors, pharmacists need to get the message that a serious situation is developing around misfilled prescriptions. Pharmacists must develop checks and balances that will help prevent medication errors from occurring and must utilize errors and "near misses" as learning experiences so that similar errors will be avoided in the future.

I believe it is safe to say that, as a general rule, a patient would rather get a correct prescription later rather than a wrong prescription immediately. Time spent making sure a prescription is correct is time well spent.

Technician Registration

Board of Pharmacy inspectors continue to report some confusion on the part of pharmacists and pharmacy technicians on the issue of whether a technician must be registered with the Board of Pharmacy before they begin work or whether they can be "in training" without being registered.

Board of Pharmacy rules do not allow a period of work as a technician-in-training without being registered with the Board. Just as with the case of pharmacist-interns, pharmacy technicians must register with the Board before they begin to perform any technician functions. There is no allowance for individuals to work as a "technician-in-training" without being registered.

Technician and Pharmacist Renewals

The renewal period for pharmacy technicians, December 31/January 1, and for pharmacists, February 28/March 1, has recently ended. Some registrants and licensees have complained that they did not receive their renewal applications in a timely fashion. Investigation of the complaints, however, often revealed that the individuals involved had requested that their renewals be sent to their work address, and then they neglected to notify the Board of a change of employment. As a result, the licensed renewals were sent to their previous place of employment, and the renewals were delayed in reaching the individuals.

Similarly, some pharmacists and technicians have indicated that they want their renewals sent to their current place of employment but because of the volume of mail arriving at the pharmacy and the work schedule of the individuals involved, the individuals were again delayed in receiving their renewals.

Pharmacists and technicians are strongly urged to request that the renewals of licenses and registrations be sent to their home address rather than to the pharmacy. An employment address can still be used as the "public address," but the renewals, and only the renewals, can be designated to be sent to a home address.

Both pharmacists and technicians are required to notify the Board of changes in employment, but it is common for individuals to forget to make that notification. When renewal applications are designated to be sent to the work address in these situations, delays in receiving the renewals often occur and late fees are assessed.

June Board Exam Dates and Deadlines

The Board will be offering the practical part of the full Board examination on Tuesday, June 4, 2002. The deadline for applying to sit for the June examination is April 19, 2002.

Pharmacy students who plan on taking the June Board exam for licensure in Minnesota should be requesting examination applications immediately, if they have not already done so. Because the deadline for application submission occurs prior to the date of graduation from most colleges of pharmacy, final acceptance as a candidate to sit for the Board exam will not be made until graduation is confirmed by an applicant's college of pharmacy.

Potential employers of new graduates are cautioned not to schedule the individuals taking the June Board exam for work as pharmacists until the individual has received confirmation on passing the Board exam and has paid the original license fee. Only then can individuals begin their careers as pharmacists in Minnesota.

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David E. Holmstrom, JD, RPh - State News Editor

Carmen A. Catizone, MS, RPh - National News Editor & Executive Editor

Courtney M. Karzen - Editorial Manager

MINNESOTA BOARD OF PHARMACY

National Association of Boards of Pharmacy Foundation, Inc
700 Busse Highway
Park Ridge, Illinois 60068

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